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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,451	09/20/2003	Shuyi Zhang		4516

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,451	ZHANG ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected because they do not identify the structure, material, or acts set forth in the specification that would be capable of carrying out the functional properties recited in the claims. It appears from the specification that the claimed release profile is achieved from formulations that contain specific structure. For example, specific amounts of ingredients in the immediate release dosage, or specific sustained release polymer in the sustained release dosage (see examples 1-3). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, the structure which results in the claimed release profile, must be clearly and positively specified.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raffa et al. US 5,336,691, in view of Kaiko et al. US 6,375,957.

Raffa teaches a composition comprising tramadol and acetaminophen (abstract; and column 3, lines 10 through column 4, lines 1-8). The composition further comprises pharmaceutical carrier for oral administration (column 4, lines 42-49).

Raffa does not explicitly teach the claimed dosage form, which contains combination of immediate release and sustained release portions of the drugs.

Kaiko teaches an oral dosage form comprising combination of about 15 mg to about 360 mg opioid analgesic and from about 25 mg to about 1000 mg acetaminophen (abstract; claims; column 5, lines 6-14; and column 14, lines 27-45). Opioid analgesic includes tramadol (column 12, line 2; and claim 6). The dosage form can formulated as

tablet, capsule, granule, bead, or multiparticulate (column 19, lines 31-45; and column 20, lines 8-10). Kaiko further teaches dosage form comprises both immediate and sustained release multiparticulates to achieve a desired effect (column 7, lines 44-46; and column 30, lines 50-63). The sustained release dosage form further includes from about 1% to about 80% sustained release carrier (hydrophobic polymer), and may optionally be coated with one or more materials suitable for the regulation of release or for the protection of the formulation (column 21, lines 1-61; and column 26, lines 43-55). Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Raffa using the oral dosage form in view of the teaching of Kaiko, because Kaiko teaches an oral dosage form suitable for combination of tramadol and acetaminophen, because Kaiko teaches an oral dosage form suitable for the treatment of pain in human patients while reducing the oral abuse potential, and because Raffa teaches oral dosage form such as tablet or capsule that can be coated (column 4, lines 56-65).

It is noted that the cited references do not expressly teach the percent amounts of the dosage forms. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Hence, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amounts of immediate release and

sustained release portions of the dosage form taught by Kaiko to obtain the claimed release profile, because Kaiko teaches combination of immediate release and sustained release portions in the same dosage form, and because Kaiko teaches the use of the claimed gel polymer in the sustained release portion to delay the release of the drugs for a time period of from about 8 to about 24 hours (column 29, lines 52-54).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Faour et al. is cited as of interest for the teaching of dosage form comprising combination of different drugs, and combination of immediate and controlled release portions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1615